

REMARKS

This responds to the Office Action dated 17 August 2011. Claims 1-41 are pending in the application. Claims 31-37 have been withdrawn. No new matter has been added.

Claim Rejections – 35 U.S.C. §103

Claims 1-30 and 38-41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,545,178 to Kensey et al. in view of U.S. Published Application No. 2002/0183787 to Wahr et al. and U.S. Published Application No. 2003/0176890 to Buckman et al. Applicant respectfully traverses this rejection.

Claim 1 recites, “the ratchet mechanism including a first member that maintains a fixed position relative to the filament and terminates proximal of a distal end of the filament.” Claim 12 recites, “wherein the filament provides a pivotal connection of the internal component to the first member distally of the ratchet mechanism.” Claim 20 recites, “wherein the filament provides a pivotal connection of the anchor to the first member distally of the ratchet mechanism.” Claim 28 recites, “wherein the strap and hub comprise a ratchet mechanism . . . ; wherein the strap and locking hub are separate from the filament, anchor and sealing plug and are positioned proximal of the anchor and a distal end of the filament.”

Kensey discloses with reference to FIGS. 1-5 a device 20 used to close and seal a tissue puncture. The device 20 includes a sealing member 36, an anchoring member 38, a holding member 40, and a positioning filament 42 that interconnects the features 36, 38, 40. The holding member 40 is constructed as a disc that slides along the filament 42 to

compress the sealing member 36 toward the anchoring member 38 (*see FIGS. 6 and 7*). The holding member 40 is held in place after compressing the sealing member 36 by positioning a knot in one strand of the filament 42 on a proximal side of the holding member 40 and tying off the opposite strand of the filament 42 outside of the tissue layer (*see FIG. 5 of Kensey*). The holding member 40 is a single-piece device. There is no disclosure or suggestion by Kensey of a ratchet mechanism, much less a ratchet mechanism as part of the holding member 40 or part of the filament 42.

Furthermore, the holding member 40 moves in its entirety toward the anchor along the filament 42 to compress the sealing member 36. The holding member 40 is always positioned proximal of the sealing member 36 and does not at any time pass through any portion of the sealing member 36. There is no disclosure or suggestion by Kensey of combining the holding member 40 with any other feature to assist in compressing the sealing member 36 or maintaining the sealing member 36 in a compressed state. Further, there is no disclosure or suggestion by Kensey of connecting the anchoring member 38, sealing member 36 and holding member 40 together with anything but the filament 42.

Therefore, Kensey fails to disclose or suggest every limitation of claims 1, 12, 20 and 28 for at least the reason the reason Kensey is completely silent concerning the claimed “ratchet mechanism” and the other features of claims 1, 12, 20 and 28 discussed above.

Wahr discloses with reference to FIGS. 1 and 11 a closure device 10 that includes an anchor 12 directly connected to a tether 16. The tether 16 extends through and

connects to a second anchor 14 via a releasable fixation mechanism 30 that is carried by the second anchor 14 and directly contacts the tether 16. When released, the releasable fixation mechanism 30 permits the second anchor 14 to move along the tether 16 relative to the first anchor 12. When locked, the releasable fixation member 30 fixes a position of the second anchor 14 relative to the first anchor 12.

The Wahr apparatus fails to disclose separate features of a filament, an anchor, a sealing plug, and a two-piece locking apparatus as set forth in each of independent claims 1, 12, 20 and 28. Wahr fails to disclose at least a sealing plug and filament that are separate from the anchors 12, 14 and the fixation member 30. There is no need for a separate filament since the tether 16 is directly connected to the anchor 12. Further, the anchors 12, 14 are intended to directly contact tissue surfaces on opposite sides of a tissue opening to assist in holding a septum primum (SP) against a septum secundum (SS) (*see FIGS. 9-10*). There is no disclosure or suggestion by Wahr to use the closure device 10 to compress a sealing plug. Wahr fails to disclose or suggest providing a pivotal connection of the anchor 12 to a ratchet mechanism with a filament. Wahr fails to disclose or suggest a ratchet mechanism that terminates proximal of a distal end of a filament. As noted by the Examiner, Wahr also fails to disclose any kind of specific ratchet structure, but instead only generally suggests a ratchet mechanism.

Buckman fails to remedy the deficiencies of Wahr and Kensey as they relate to claims 1, 12, 20 and 28. Buckman discloses a ratchet device that includes a bolt 10 having a plurality of serrations 20 along at least one of its ends 18, and a pressure plate 26 with ratcheting lock 28 that ratchets along the serrations 20. There is no disclosure or

suggestion by Buckman of using a ratchet mechanism in combination with a filament, anchor, sealing plug, or two-piece locking apparatus. Thus, Buckman suffers from the same deficiencies as Wahr and Kensey as they relate to independent claims 1, 12, 20 and 28.

Both Wahr and Buckman fail to disclose or suggest a separate component from the tether 16 and bolt 10, respectively, for operation of a ratchet feature. The Examiner contends that “one skilled in the art would have a choice between providing a separate ratchet strap (similar to the strap disclosed in Buckman) along a portion of the filament 42, or alternatively, to integrally form ratchet teeth along the filament 42 itself so as to form a ratchet strap that is integral with the filament 42” of the Kensey device. Applicant respectfully disagrees.

Applicant submits herewith the Declaration of Zachary Tegels, one of ordinary skill in the art. Mr. Tegels explains that “the filaments used in vascular closure devices are generally flexible structures having a small cross section that would *prohibit* formation of features within the filaments such as notches or steps used as ratchet features.” *See* paragraph 4, lines 1-3. Mr. Tegels also explains that “any attempt to add such features to the filament, even if such a modification were possible, would weaken the filament and render it useless for its intended purpose of holding together the anchor and sealing pad.” *See* paragraph 4, lines 3-6. Thus, there would be no motivation for one of skill in the art to form ratchet teeth in the filament 42 of Kensey.

Mr. Tegels further explained, upon reviewing the Wahr and Buckman references, that “persons of ordinary skill in the art of vascular closure devices (*e.g.*, the device

disclosed by Kensey) would have no motivation to look to the devices of Wahr and Buckman in considering how to improve a vascular closure device.” *See paragraph 5, lines 3-6.* Mr. Tegels confirms Applicant’s previously submitted arguments that “Wahr only discloses a ratchet mechanism generally with no disclosure or suggestion whatsoever of combining the ratchet mechanism with a vascular closure device or the type of filament used with vascular closure devices.” *See paragraph 6, lines 10-13.* Mr. Tegels also explains that the Buckman device is “so far removed from vascular closure devices that those of skill in the art of vascular closure devices, such as myself, would have no motivation to reference Buckman, much less incorporate features of Buckman into, a vascular closure device.” *See paragraph 7 lines 7-10.* Mr. Tegels also asserts relative to Buckman that “even if one of skill in the art were to reference the Buckman device, there is no suggestion whatsoever by Buckman of using a ratchet mechanism in combination with a filament, sealing plug, or two-piece locking apparatus.” *See paragraph 7, lines 10-12.* He summarizes his analysis by stating that “based on my review of Kensey, Wahr and Buckman, there is clearly no teaching, motivation or suggestion to replace the holding member 40 of Kensey with one of the ratchet mechanisms of Wahr and Buckman.” *See paragraph 8, lines 9-11.*

Applicant submits that Mr. Tegels’ analysis, as one of ordinary skill of vascular closure devices, concerning the lack of motivation to combine Wahr and Buckman with Kensey is additional compelling support for the nonobviousness of claims 1, 12, 20 and 28.

In view of the above, Applicant submits that Kensey, Wahr and Buckman, alone or in combination, fail to disclose or render obvious every limitation of claims 1, 12, 20 and 28, and the claims that depend from them.

Conclusion

For at least the foregoing reasons, Applicant believes that each of the presently pending claims in this application is in immediate condition for allowance. Accordingly, Applicant respectfully requests a favorable action on the merits. If the Examiner has any further comments or suggestions, Applicant invites the Examiner to telephone the undersigned attorney to expedite the handling of this matter.

Applicant expressly disclaims all arguments, representations, and/or amendments presented or contained in any other patent or patent application, including any patents or patent applications claimed for priority purposes by the present application or any patents or patent applications that claim priority to this patent application. Moreover, all arguments, representations, and/or amendments presented or contained in the present patent application are only applicable to the present patent application and should not be considered when evaluating any other patent or patent application.

The Commissioner is hereby authorized to charge any additional fees which may be required for this application, or credit any overpayment, to Deposit Account No. 08-2623. If any extensions of time are needed for timely acceptance of these documents, such an extension is hereby requested and payment of any such extension fees is authorized from Deposit Account No. 08-2623.

Respectfully submitted,

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